Feasibility of lumbar supports for home care workers with low back pain

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The aims of this study were to assess the compliance of home care workers with low back pain (LBP) in using a lumbar support, to establish the benefit experienced from the support, and to determine the predictive factors for that compliance and benefit. Only home care workers who had LBP at the start of the study or who had experienced at least two episodes of LBP in the 12 months prior to the study could apply for participation. The study consisted of two phases. In phase I (the first week of the study), workers used the lumbar support each working day. In phase II (the following 6 months), subjects were instructed to use the lumbar support only on those working days when they experienced LBP. Weekly questionnaires were used to measure compliance; monthly questionnaires were used to measure the benefit experienced. Fifty-nine workers participated in the study. Overall, they scored their perceived benefit from the lumbar support as 7 on a scale of 0–10, and 61–81% of the workers were compliant. Multiple linear regression analysis showed that the best predictor for experienced benefit is the degree of confidence in expected pain reduction due to the lumbar support, measured after phase I (R^2 = 0.70). Multiple logistic analysis showed that the best predictor for compliance is the extent to which subjects consider they can influence their own health status (R^2 = 0.49). Because both the benefit experienced and the compliance rate were substantial, the use of lumbar supports by home care workers with LBP seems feasible. However, we cannot recommend extensive use of lumbar supports in home care workers with LBP based solely on the results of the present study. First, there is a clear need for a randomized clinical trial on this topic.

Key words: Back pain; home care; lumbar support.

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Introduction

Although lumbar supports are frequently used for the prevention and treatment of low back pain (LBP) [1], their effectiveness remains debatable [1–5]. A recent systematic review showed that there is no evidence in favour of the use of lumbar supports for primary prevention of LBP in the workplace [6]. For workers with a history of LBP and those with LBP at baseline, however, some promising findings have been reported [6]. Conflicting evidence was found for the effectiveness of lumbar supports for treatment of LBP [6]. In particular, only four of the 13 studies included in the review by Van Tulder *et al.* [6] presented data on compliance, including two studies showing a very low compliance rate. Thus, it remains unclear whether, and to what extent, the results of these studies may have been influenced by non-compliant participants. Measuring compliance is important not only for detecting a possible source of bias, but also for ascertaining the feasibility of lumbar supports as an intervention for LBP.

LBP is a major health problem among Western industrialized countries, and is a major cause of medical expenses, absenteeism and disablement [7]. One occupa-

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tional group in which many suffer from LBP is home care workers. While the yearly prevalence of LBP has been reported to range from 25 to 40% in European industrialized countries [8], this percentage has been reported to be even higher in home care, at 44–72% [9–11]. This relatively high figure may be explained, at least in part, by the many physical, psychological and psychosocial risk factors for LBP in the activities undertaken by home care workers. For example, a study conducted in Rotterdam showed that carrying/lifting a load of ≥5 kg, frequent bending/twisting, heavy physical work and job dissatisfaction are significantly associated with LBP [9].

In view of the large number of home care workers troubled by LBP, their physical workload, the promising findings of lumbar supports for secondary prevention and the conflicting data on their therapeutic use, home care workers seem to be a highly appropriate population in which to investigate the use of lumbar supports by those experiencing LBP in the workplace. However, before a randomized trial on the effectiveness of lumbar supports in this population is conducted, insight is required into the feasibility of using lumbar supports in home care. The aims of the present study were therefore to: (i) determine the compliance with using a lumbar support in home care workers with LBP complaints; (ii) establish the benefit experienced from using the support; and (iii) determine the factors that could predict that compliance and benefit.

Methods

Design

The present study was designed as a prospective cohort study in which all subjects received a lumbar support as intervention for LBP. The intervention period consisted of two phases: phase I, which lasted for 1 week, and phase II, which comprised the following 6 months. Phase I allowed subjects to get used to wearing a lumbar support; in this phase, subjects were instructed to wear the support each working day. During the 6 months of phase II, subjects were instructed to wear the support only on those working days when they experienced LBP. The use of the lumbar support was supplementary to the usual care given by physicians and/or therapists. The study was approved by the Medical Ethical Committee of the Erasmus University Rotterdam, The Netherlands.

Subjects

Employees of a home care organization in Amstelveen, The Netherlands, could apply for participation when they met the following inclusion criteria: (i) performing physical care and/or household tasks as home care activities; and (ii) reporting LBP at the start of the study, or two or more episodes of LBP in the 12 months prior to the start of the study. However, in view of the possible relationship between lumbar supports, increased blood pressure and increased heart rate [12], workers under medical treatment for high blood pressure were excluded from participation.

Workers could apply for participation directly to the researcher, or indirectly via their home care manager. After checking the inclusion criteria by telephone, final enrolment took place.

Intervention

In this study, two different lumbar supports were used: the Lumboloc® and the Lumbotrain Lady® (Bauerfeind Benelux BV, Haarlem, The Netherlands). These supports were chosen because of their cut (the Lumbotrain Lady® is specially designed for women), and because both models can be worn on top of or under daily clothes. The Lumboloc® is made of elastic material, has metal stays in the back and is available in six sizes. The Lumbotrain Lady® is also made of elastic material, but has a silicone rubber pad in the back and is available in five sizes. During a meeting with one of the researchers (P.J.), subjects received details about the study, and the lumbar support model that fitted closest to the lower back was selected for the study.

Outcome measures

At baseline, subjects completed a questionnaire (available from the corresponding author) on demographic data, history of back pain, health status measured by the Coop Wonca [13,14], back-pain-specific functional status measured by the Quebec Back Pain Disability Scale (QBPDS, Dutch translation) [15,16], body mass index (BMI) and type of activities performed at work during the previous week. Using a 0–10 numerical rating scale, subjects were also asked to rate their degree of confidence that a lumbar support would reduce their pain and improve their functioning during an LBP episode (0 = no confidence at all, 10 = unlimited confidence).

After 1 week (phase I), subjects scored their satisfaction with the lumbar support (0–10; 0 = very discontented, 10 = very contented), and also scored several items regarding feasibility (on a five-point Likert Scale; 1 = complete disagreement, 5 = complete agreement, OR yes/no). In addition, they again rated their confidence in pain reduction and functional improvement (0–10).

In phase II, the subjects filled out weekly and monthly questionnaires. The weekly questionnaires addressed the number of working hours (hours), LBP (hours), LBP at work (hours), time lost from work (hours), time lost from work due to LBP (hours), use of lumbar support at work (hours) and use of lumbar support at home (yes/no) that week. The monthly questionnaires concerned health care

use, degree of LBP during the previous week (0–10; 0 = no pain at all, 10 = worst imaginable pain), back-pain-specific functional status (QBPDS), activities at work, the degree to which these activities were experienced as severe for their back, and the degree of benefit experienced by the lumbar support (0–10; 0 = no benefit at all, 10 = maximum benefit). Finally, they were asked to evaluate several statements on the feasibility of lumbar supports (on a five-point Likert Scale). Four items addressed 'pain reduction' (e.g. 'the lumbar support makes my LBP more bearable'), three addressed 'benefit at work' (e.g. 'the lumbar support supports my back during lifting'), two asked for 'overall opinion' (e.g. 'I can recommend the lumbar support to colleagues suffering from LBP') and eight covered 'comfort' (e.g. 'I can sit comfortably with the lumbar support').

Data analysis

Compliance

We defined compliance as the percentage of subjects who used the lumbar support at work for ≥80% of the weeks in which they reported LBP at work. Subjects who withdrew from the study for reasons other than being pregnant or quitting their job were considered as non-compliant. Additionally, the percentage of subjects with LBP at work who used the lumbar support at work was calculated per week, and these weekly percentages were averaged over 6 months ('alternative compliance').

Benefit

The benefit that subjects experienced from the lumbar support was measured on a 0–10 scale. Most items on feasibility also refer to benefit. Mean group scores of experienced benefit and feasibility items were calculated by first determining the mean score over 6 months per subject and subsequently averaging these scores over all subjects. In this way the scores of drop-outs weighted as much as the scores of the other subjects. The five-point Likert Scale of the feasibility items was eventually transformed to a three-point Likert scale: disagreement/no disagreement or agreement/agreement.

In addition, we calculated the change in pain intensity and functional status. The values for pain intensity and functional status measured at the end of the 6 month intervention period were compared with those measured at baseline. In the case of absence of data for the last month (i.e. the sixth month), data from the last returned questionnaire were used.

Predictors of compliance and benefit

To detect predictors of compliance and experienced benefit, the following factors were used in the statistical analysis: all items measured by the baseline questionnaire (like BMI), mean degree of LBP, mean degree of functional disability and items addressing activities at work. In addition, all items of the phase I questionnaire, items on feasibility of the lumbar support measured by the monthly questionnaires, and mean degree of benefit experienced were also used as predictors of compliance; degree of confidence in pain reduction and functional improvement, satisfaction with the lumbar support measured after 1 week, and compliance rate were also used as predictors of experienced benefit.

Statistical analysis

Logistic regression analysis was used to determine factors predicting compliance; linear regression analysis was used to identify factors predicting benefit. Both analyses were first conducted univariately, followed by multivariate analysis. Only factors that univariately showed a significant relationship with compliance or benefit and had <20% missing values were used in multivariate analyses. We used this strict condition in order to restrict the number of independent variables relative to the number of cases. Statistical significance was measured at $P \leq 0.05$.

Results

Subjects

After checking the inclusion and exclusion criteria by telephone, two of the 62 people who had applied for study participation were excluded; one was receiving medical treatment for high blood pressure, while the other did not have two episodes of LBP in the last 12 months nor had LBP at the start of the study. During baseline measurement, another subject withdrew because she did not have *low* back pain. Thus, at this stage, there were 59 participants.

Characteristics of the study population are given in Table 1. The mean age at baseline was 39.1 years. The majority were women (98%), 86% had LBP at baseline and 52% had visited a physician because of LBP in the 12 months before baseline measurement.

Phase I

Of the 59 subjects, 26 (44%) chose the Lumbotrain Lady® and 33 (56%) the Lumboloc®. During phase I, three subjects (5%) withdrew from the study because of inflammation of a navel piercing ($n = 1$), deterioration of existing knee problems ($n = 1$) and the advice of a chiropractor ($n = 1$). All remaining 56 subjects completed the first week and returned the questionnaire.

During phase I, compliance (defined as the number of days that the subjects used the lumbar support at work divided by the number of days that the subjects worked)

was 96%. Satisfaction with the lumbar support was scored (average) as 6.5 (0–10). Feasibility data showed that 89% agreed that the lumbar support indeed supported their back during lifting, 85% agreed that it made them aware of a proper lifting technique and 73% indicated that they would like to adapt the lumbar support. More than half of these subjects indicated that the lumbar support was too tall.

Phase II

During the following 6 month intervention period, another 10 subjects (17%) withdrew from the study: four (7%) withdrew because they no longer worked in home care; two (3%) became pregnant; and the remaining four workers (7%) had diaphragmatic hernia, shortness of breath, pain in the abdominal area, or experienced more problems than benefit with the lumbar support, respectively. In phase II, 1354 of the 1472 questionnaires (92.0%) were returned.

Table 1. Baseline characteristics of study population (n = 59)

Characteristic	*Mean ± SD*	*No. (%)*
Age (years)	39.1 ± 9.1	
Sex: female		58 (98.3)
Employment in current home care (years)	7.6 ± 6.8	
Tasks in home care		
Only physical care (like showering patients)		23 (39.0)
Only household activities (like vacuum-cleaning)		3 (5.1)
Physical care and household activities		33 (55.9)
Contact with physicians during the last 12 months because of LBP		
Never		28 (47.5)
1–2 times		20 (33.9)
3–5 times		6 (10.1)
>5 times		5 (8.5)
Subjects with LBP at baseline or in the week before		51 (86.4)
Location of their LBP		
Low back		26 (51.0)[a]
Low back & pain radiating to one thigh/leg		21 (41.2)[a]
Low back & pain radiating to two thighs/legs		4 (7.8)[a]

[a] n = 51; only subjects who had LBP in the week before baseline measurement answered this question.

Compliance

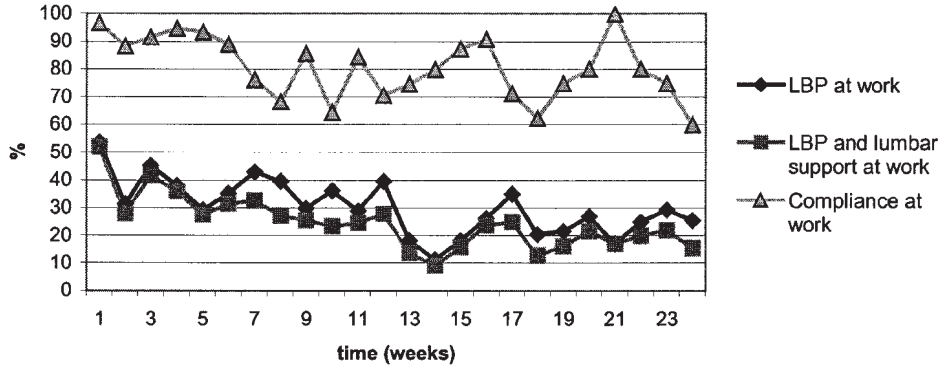
Sixty-one per cent of the workers used the lumbar support at work for ≥80% of the weeks in which they reported (at least 1 day of) LBP at work. The alternative way to calculate compliance shows that 81% of all subjects who reported (at least 1 day of) LBP at work in a certain week actually used the lumbar support at work that week. Figure 1 shows the curve of this 'alternative compliance', the number of workers with LBP at work and the number of workers with LBP at work who actually used the lumbar support at work.

Although we instructed subjects to use the lumbar support only on those working days that they experienced LBP, data from the weekly questionnaires showed that 31% of the subjects without LBP (at work) still used the lumbar support at work. On average, 23% of all subjects reported use of the lumbar support at home.

Benefit

Subjects scored the benefit they experienced as 7 on a 0–10 scale. The most striking results on feasibility items are: 86% of the subjects agreed that the lumbar support supported their back during lifting; 88% said that it made them more aware of a proper lifting technique; 76% thought that the lumbar support made their LBP more bearable; 88% also wanted to use the lumbar support after completion of the study; and 88% agreed that they would recommend the lumbar support to colleagues suffering from LBP. On the other hand, 76% disagreed that it is possible to sit comfortably with a lumbar support

Figure 1. Percentage of subjects who reported LBP at work, percentage who reported LBP at work and actually used the lumbar support at work, and the fraction of these percentages: compliance ('alternative compliance').



and 88% disagreed that a lumbar support causes annoying skin irritation.

During the intervention period, there was a 44.6% decrease in pain intensity. While the mean pain intensity at baseline was 4.2 ± 2.5 (mean ± SD; n = 59) on a 0–10 scale, after the intervention period the mean pain intensity was 2.3 ± 2.9 (n = 59). Disability due to LBP also decreased. At baseline, the degree of disability was 29.3 ± 18.9 on a scale of 0–100 (n = 59) and fell to 16.3 ± 22.1 (n = 59) after the intervention period—a decrease of 44.3%.

Predictors of compliance and benefit

Univariate regression analysis showed that several factors could predict the benefit experienced and compliance during the 6 month follow-up (Table 2). Significant associations were found between benefit experienced and confidence at baseline in reduction of pain [with an explained variance (R^2) of 0.08], confidence in reduction of pain after 1 week (R^2 = 0.70), confidence in improved functioning after 1 week (R^2 = 0.49), satisfaction with the lumbar support after 1 week (R^2 = 0.40) and mean degree of LBP (R^2 = 0.18).

For compliance, significant univariate associations were found for the presence of emotional problems in the 2 weeks before baseline (R^2 = 0.13), the degree to which subjects think they can influence their health by their own behaviour (R^2 = 0.17), BMI (R^2 = 0.15), subjects' desire to change the lumbar support after 1 week

Table 2. Predictors of mean experienced benefit (0–10 NRS) and compliance rate (yes/no)[a]

		Univariate analysis			*Multivariate analysis*		
Predictors of mean experienced benefit	*Direction of association*	*B (SE)*	*P*	*n*	*B (SE)*	*P*	*n*
Confidence in reduction of pain by a lumbar support, measured at baseline (0–10 NRS)	↑ confidence–↑ benefit	0.28 (0.14)	0.04	49[b]	NS[c]		
Confidence in reduction of pain by a lumbar support, measured after phase I (0–10 NRS)	↑ confidence–↑ benefit	0.82 (0.08)	0.00	48	0.88 (0.17)	0.00	48
Confidence in improvement of functioning during a LBP episode by a lumbar support, measured after phase I (0–10 NRS)	↑ confidence–↑ benefit	0.70 (0.11)	0.00	48	NS		
Satisfaction with the lumbar support, measured after phase I (0–10 NRS)	↑ satisfaction–↑ benefit	0.60 (0.11)	0.00	48	NS		
Degree of LBP, averaged over 6 months (0–10 NRS)	↑ degree of LBP–↑ benefit	0.39 (0.13)	0.01	42	–[d]		
Predictors of compliance rate		*OR (95% CI)*	*P*	*n*	*OR (95% CI)*	*P*	*n*
Presence of emotional problems in the 2 weeks before baseline, measured by a Coop Wonca chart at baseline (1–5 Likert Scale)	↑ emotional problems–↓ compliance	0.52 (0.30–0.91)	0.02	56[e]	NS		
Degree to which subjects think they can influence their health by their own behaviour, measured at baseline (1–4 Likert Scale)	↑ influence–↓ compliance	0.32 (0.13–0.81)	0.02	56	0.12 (0.02–0.72)	0.02	48
Body Mass Index	↑ BMI–↓ compliance	0.83 (0.71–0.97)	0.02	56	NS		
Wish to change something to the lumbar support, measured after phase I (yes/no)	yes–↓ compliance	0.19 (0.04–0.96)	0.05	53	NS		
Mean score on Quebec Back Pain Disability Scale, averaged over 6 months (1–6 Likert Scale)	↑ disability–↑ compliance	2.89 (1.0–8.1)	0.04	42	–		
Opinion on 'lumbar support is too warm', averaged over 6 months (1–5 Likert Scale)	↑ warmth–↑ compliance	2.59 (1.0–6.4)	0.04	48	NS		

The regression coefficient (B), standard error (SE), odds ratio (OR), 95% confidence interval of OR (95% CI), significance value (P) and number of subjects are presented per predictor.

[a]Subjects were considered compliant when they used the lumbar support at work in ≥80% of the weeks in which they reported LBP at work.

[b] Since five subjects never used the lumbar support and five withdrew from the study before filling in a monthly questionnaire, linear regression analysis was assessed with data of maximal 49 subjects.

[c]NS, not significant.

[d]Not included in the multivariate analysis because of the high number of missing values (≥20%).

[e]Since three subjects never experienced LBP, logistic regression analysis was assessed with data of maximal 56 subjects.

(R^2 = 0.13), mean functional disability (R^2 = 0.15) and the degree to which subjects think the support is too warm (R^2 = 0.14).

'Mean degree of LBP' and 'functional disability' were excluded from the multivariate analyses because >20% of values were missing. Multiple linear regression analysis shows that the best predictor for the benefit experienced is the degree of confidence in pain reduction by the lumbar support measured after phase I (R^2 = 0.70). Multiple logistic analysis shows that the best predictor for being compliant is the extent to which subjects consider they can influence their own health status (R^2 = 0.49).

Discussion

Compliance

Compliance rate is an important aspect when considering the feasibility of an intervention. In the present study, compliance ranged from 61 to 81%, depending on the way it was calculated. When calculated at the level of the individual, compliance was 61%, whereas at the group level it was 81% ('alternative compliance'). It is noteworthy that, even though they were not instructed to do so, several participants who were not troubled by LBP still used the lumbar support at work, and several used it at home. Thus, although this pilot study was intended to investigate lumbar supports used as a mode of treatment for LBP, subjects also used the support for secondary prevention.

A comparison between our compliance rate and that of other studies is difficult, because only one of the seven randomized clinical trials on the effectiveness of lumbar supports for treatment of LBP presents data on compliance [6]. Pope *et al.* [17] reported that 65% of their subjects used the lumbar support for >7 h a day during the intervention period of 3 weeks. Penrose *et al.* [18] reported that their subjects had no difficulty wearing the device for the required time, but they did not present any actual data. Comparison between our compliance rate and those found in randomized clinical trials on prevention shows that our rate is considerably higher than that reported by Van Poppel *et al.* [19] and Reddell *et al.* [20]; this was to be expected, however, because subjects with a history of LBP may be more inclined to use a lumbar support than subjects without. In a non-randomized trial, Anderson *et al.* [21] reported a compliance rate similar to ours, but in their study, the compliance rate was reported by supervisors.

Benefit

The benefit experienced from using the lumbar support is another important aspect when considering the feasibility of an intervention. In the present study, subjects scored the benefit experienced as 7 (on a 10-point scale). Although most feasibility items showed positive results, the impossibility of sitting comfortably with a lumbar support was frequently reported by our subjects and also by Van Poppel *et al.* [19]. Pain intensity and functional disability decreased during the study.

Predictors of benefit and compliance

Multivariate linear regression analysis showed that confidence in pain reduction by a lumbar support, measured after 1 week of use of the support, is a very strong predictor of the benefit experienced in the following months.

Multiple logistic analysis on compliance showed that the degree to which subjects see themselves able to influence their own health status is a strong predictor. Interestingly, the less subjects consider they are able to influence their own health, the more compliant they are. According to the locus of control theory of Rotter [22], these subjects are 'externals' (external locus of control). Unlike individuals with an internal locus of control, externals do not believe they can have an impact upon their outcomes (e.g. health) through their behaviour. This might be why they rely more on external aids, such as lumbar supports. According to Halfens [23], there are indications that intervention programmes based on an internal locus of control tend to be more beneficial to internally controlled people, while the opposite seems to be true for externally controlled people.

Limitations of the study design

The design of the present study did not include a control group, nor were subjects acquired by random sampling. Results regarding benefit experienced and compliance might have been biased by factors such as the number of drop-outs, and the expectations and motivation of the worker and home care manager.

The number of drop-outs was considerable, although almost 50% of them withdrew for reasons not related to the use of the lumbar support. By weighting the mean scores of drop-outs as heavily as the mean scores of the other subjects, we probably minimized the possible bias of the number of drop-outs. Given the relatively high percentage of returned questionnaires, participants were probably highly motivated. Home care managers considered the present study to be important and gave considerable attention to our study in meetings with their workers. All these factors imply that one should be cautious about generalizing these results to other populations.

Although both the benefit experienced and the compliance rate were substantial, we cannot recommend the extensive use of lumbar supports in home care workers with LBP based on these results. However, in view of the

promising findings in this study, there is a clear need for a randomized clinical trial on this topic, in which optimization of compliance, measurement of the confidence in the intervention and investigation of the locus of control should be important issues.

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